

CIVIL CASE INFORMATION STATEMENT
CIVIL CASES

2015 MAR 18 11:10:01
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In the Circuit Court, Kanawha County, West Virginia

I. CASE STYLE:

Plaintiff/Petitioners,

Case # 15-C-1569

STATE OF WEST VIRGINIA ex rel.
PATRICK MORRISEY,
ATTORNEY GENERAL,

Judge Welster

v.

Defendants.

Days to
Answer

Type of Service

AMGEN INC.

Original and ____ copies of complaint furnished herewith.

(Continued On Next Page)

PLAINTIFF: STATE OF WEST VIRGINIA ex rel.
PATRICK MORRISEY, ATTORNEY GENERAL

CASE NUMBER:

DEFENDANTS: AMGEN INC.

II. TYPE OF CASE:

TORTS	OTHER CIVIL

Asbestos	Adoption	Appeal from Magistrate Court
Professional Malpractice	Contract	Petition for Modification of Magistrate Sentence
Personal Injury	Real Property	Miscellaneous Civil
Product Liability	Mental Health	X Other
Other Tort	Appeal of Administrative Agency	

III. JURY DEMAND: Yes No X

CASE WILL BE READY FOR TRIAL BY (MONTH/YEAR): N/A

IV. DO YOU OR ANY OF YOUR CLIENTS OR WITNESSES IN THIS CASE
REQUIRE SPECIAL ACCOMMODATIONS DUE TO A DISABILITY OR AGE?

YES NO X

IF YES, PLEASE SPECIFY:

Wheelchair accessible hearing room and other facilities
Interpreter or other auxiliary aid for the hearing impaired
Reader or other auxiliary aid for the visually impaired
Spokesperson or other auxiliary aid for the speech impaired
Other: _____

Attorney Name: Michael M. Morrison, Assistant Attorney General
(State Bar No. 9822)

Firm: State of West Virginia, Attorney General's Office

Address: Post Office Box 1789, Charleston, WV 25326-1789

Telephone: (304) 558-8986

Representing:

X Plaintiff

Defendant

Cross-Complainant

Cross-Defendant

Dated: August 18, 2015.

Signature

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

2015 MAR 18 11:10:01

Clegg

STATE OF WEST VIRGINIA
ex rel. Patrick Morrissey,
Attorney General,

Plaintiff,

v.

Civil Action No.:

15-C-1569
Webster

AMGEN INC.,

Defendant.

COMPLAINT

1. Plaintiff, State of West Virginia, in its sovereign capacity, by and through Patrick Morrissey, Attorney General of the State of West Virginia, ("Attorney General" or "State") brings this action against Defendant Amgen, Inc. ("Defendant or Amgen") for violating the West Virginia Consumer Credit and Protection Act (hereinafter the "Act"), W. Va. Code §§ 46A-1-101, *et seq.*

2. The Attorney General brings this action pursuant to the Act, in the public interest, to protect the public's health, safety and welfare and pursuant to his general statutory and common law authority powers and duties pursuant to W. Va. Code § 46A-7-101, *et seq.* The Attorney General has reason to believe that the above-named Defendant has violated and/or is continuing to violate the Act. The Attorney General also has reason to believe that this action is in the public interest.

3. Upon interest and belief, the State of West Virginia alleges as follows:

JURISDICTION AND VENUE

4. This Court has jurisdiction over Amgen pursuant to Article VIII, Section 6 of the West Virginia Constitution and W. Va. Code § 51-2-2 because Amgen has transacted business within the State of West Virginia at all times relevant to this Complaint.

5. Venue for this action properly lies in Kanawha County, West Virginia, pursuant to W. Va. Code § § 46A-7-114 and 56-1-1 because Amgen transacts business in Kanawha County, West Virginia and/or some of the transactions out of which this action arose occurred in Kanawha County, West Virginia.

PARTIES

6. Plaintiff, State of West Virginia, ex rel. Patrick Morrissey, Attorney General, is charged with enforcing the Act, which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Pursuant to the Act, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the Act and to secure such equitable and other relief as may be appropriate in each case.

7. Defendant Amgen Inc. is a Delaware corporation with its principal place of business at 1 Amgen Center Drive in Thousand Oaks, California 91320. At all relevant times, Amgen did business in West Virginia by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

COMMERCE

8. West Virginia Code section 46A-6-102(6) defines “trade” or “commerce” as “the advertising, offering for sale, sale or distribution of any goods or services and shall include any trade or commerce, directly or indirectly, affecting the people of this state.”

9. Amgen was, at all times relative hereto, engaged in trade or commerce in the State

of West Virginia by marketing, selling, and promoting the biologic medications Aranesp® and Enbrel®.

ALLEGATIONS

ARANESP

10. Aranesp ® (darbepoetin alfa) is a biologic medication used to treat certain types of anemia by stimulating bone marrow to produce red blood cells. It belongs to a class of drugs called erythropoiesis-stimulating agents or ESAs.

11. Aranesp is approved to treat anemia caused by chronic renal failure (CRF) and chemotherapy-induced anemia (CIA) at a specified dose and frequency.

12. Aranesp's main competitor is Procrit, an ESA produced by Johnson & Johnson. Procrit has a shorter half-life and is dosed more frequently than Aranesp.

13. To better compete against Procrit, Amgen promoted Aranesp to treat anemia caused by CRF and CIA at dosing frequencies longer than the FDA approved label.

14. At the time Amgen promoted extended dosing frequencies, it lacked competent and reliable scientific evidence to substantiate the extended dosing frequencies.

15. Aranesp has never been FDA approved to treat anemia caused by cancer (Anemia of Cancer or AOC), which is distinct from anemia caused by chemotherapy.

16. Patients with AOC have active malignant disease and are not receiving chemotherapy or radiation.

17. Amgen promoted Aranesp to treat AOC even though it lacked competent and reliable scientific evidence to substantiate such use.

18. In 2001, when Amgen came on the market, Procrit was being used to treat AOC.

19. In order to compete with Procrit in the AOC market, Aranesp had to be

reimbursable by insurance companies and federal programs.

20. The most common way to obtain reimbursement for an off-label use is to obtain a listing in a CMS recognized drug compendium.

21. A drug compendium is typically a non-profit reference book listing drug strengths, quality, and ingredients.

22. In 2003, there were two main compendia recognized by CMS: American Hospital Formulary Service (AHS) Drug Information and United States Pharmacopeia (USP) Drug Information.

23. AHS did not consider Phase 2 trial data, abstracts, open label studies, or special supplements, but USP did.

24. In October of 2003, after considerable lobbying by Amgen, USP accepted an AOC indication for Aranesp. To promote Aranesp off-label to treat AOC, Amgen distributed the USP monograph (a document which describes USP's approval of the off-label use), as well as various studies that encouraged off-label use of Aranesp to treat AOC.

25. In August and October of 2003, two large randomized controlled trials found increased death and possible tumor stimulation in cancer patients receiving ESAs that were not approved in the United States.

26. In May of 2004, the FDA's Oncologic Drugs Advisory Committee met to discuss safety concerns of increased thrombotic events, tumor progression, and decreased survival seen in the 2003 studies as they applied to Aranesp and Procrit. The committee recommended large, randomized, controlled clinical trials with primary endpoints, including survival and transfusion rates to address the safety concerns.

27. Despite the growing concerns, Amgen promoted Aranesp to treat AOC.

28. In January of 2007, Amgen notified the FDA and health care professionals of the results of its pivotal 103 study in which patients receiving Aranesp for the treatment of AOC had a 28.5% increase in death and no significant reductions in transfusions or improvement in quality of life.

29. Shortly thereafter, the FDA required a black box warning on all ESAs that includes the warning “ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.” It also explicitly states to “Discontinue following the completion of a chemotherapy course.”

30. Aranesp’s label also states, “Aranesp has not been shown to improve quality of life, fatigue, or patient well-being.”

ENBREL

31. Enbrel® is Amgen’s trade name for etanercept, a tumor necrosis factor (TNF) blocker for treatment of a number of conditions, including plaque psoriasis.

32. On November 2, 1998, the FDA approved Enbrel for its first indication, the treatment of moderately to severely active rheumatoid arthritis.

33. On April 30, 2004, the FDA approved Enbrel for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

34. On February 18, 2005, the FDA sent a Warning Letter to Amgen stating that Amgen’s direct-to-consumer television advertisement entitled “Freedom” overstated the effectiveness of Enbrel, failed to communicate the limitations of Enbrel’s indication, thereby broadening the indication, and minimized the risks associated with Enbrel.

35. In March 2008, the FDA required a black box warning to be added to Enbrel's labeling. This warning informed prescribers and patients that infections, including serious infections that led to hospitalization or death, were observed in patients treated with Enbrel. These infections included cases of bacterial sepsis and tuberculosis.

36. In August 2009, the FDA required that Enbrel's black box warning be expanded to inform prescribers and patients that invasive fungal infections, as well as bacterial, viral, and other infections due to opportunistic pathogens were reported with the use of Enbrel. Additionally, the black box now warns that lymphoma and other malignancies, some fatal, have been observed in children and adolescent patients taking Enbrel.

37. Despite the black box warnings, the 2005 FDA Warning Letter, and Enbrel's limited approval for use in chronic moderate to severe plaque psoriasis, Amgen promoted Enbrel off-label for patients with mild plaque psoriasis from 2004 to 2011 and overstated Enbrel's efficacy in the treatment of plaque psoriasis.

VIOLATIONS OF LAW: UNFAIR OR DECEPTIVE ACTS OR PRACTICES

38. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 37.

39. Defendant, in the course of engaging in the marketing, promotion, selling, and distributing the biologic medications Aranesp® and Enbrel®, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under the Act by making misrepresentations about Aranesp® and Enbrel®.

40. Defendant, in the course of marketing, promoting, selling, and distributing the biologic medications Aranesp® and Enbrel®, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under the

Act, by representing that Aranesp® and Enbrel® have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of West Virginia, respectfully request that this Court:

- A. Permanently enjoin and restrain Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair, deceptive or misleading conduct, acts, or practices which violate the Act in the promotion and marketing of its biologic medications Aranesp® and Enbrel®, pursuant to W. Va. Code § 46A-7-108;
- B. Order Defendant to pay civil penalties of up to \$5,000.00 for each and every repeated and willful violation of the Act, pursuant to W. Va. Code § 46A-7-111;
- C. Order Defendant to pay all costs for the prosecution and investigation of this action, pursuant to the Act; and
- D. Grant Plaintiff such other and further relief as the Court deems equitable and proper.

Respectfully submitted,

FOR THE STATE OF WEST VIRGINIA

A handwritten signature in black ink, appearing to read 'Michael M. Morrison', is written over a horizontal line.

Michael M. Morrison (WV State Bar #9822)
Assistant Attorney General
Office of the West Virginia Attorney General
Patrick Morrissey
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Charleston, West Virginia 25326-1789